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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,778	01/30/2004	George Matlock	017761-003900US	7157

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EXAMINER
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GIBSON, ROY DEAN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/768,778	MATLOCK, GEORGE	
	<b>Examiner</b>	<b>Art Unit</b>	
	Roy D. Gibson	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-9, 15, 17-20, 22-28 and 30-35 is/are rejected.
- 7) ☐ Claim(s) 10-14, 16, 21 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/14/2005</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 15, 17, 22-27 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmer (3,948,269).

As to claims 1, 4, 5 and 15, Zimmer discloses a method of controlling a temperature of an applicator body, the method comprising:

providing an applicator body (5) that comprises at least one contact surface (distal flat end of the applicator # 2);

delivering a coolant through a conduit in at least a portion of the applicator body at a substantially constant rate;

delivering energy to at least one of the distal end of an applicator body and coolant through one or more heating elements (coil # 8) so that the contact surface of the applicator body is cooled to a desired temperature, wherein the desired temperature is about 0°C (between about – 5°C and about 3°C or wherein the desired temperature is about -2°C, and wherein the coolant is provided in a path for distributing the coolant evenly over the contact surface (col. 1, lines 34-45, col. 2, line 27-col. 3, line 29).

As to claims 17, 22-27 and 30, Zimmer discloses an applicator that delivers energy comprising:

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an applicator body comprising a proximal portion and a distal portion;  
a contact surface on the distal portion of the applicator body;  
a conduit that delivers a coolant at a constant rate on a path through at least a part of the distal portion of the applicator body; one or more heating elements coupled to the distal portion of the applicator body to deliver a heating energy to the coolant in the conduit, wherein the energy is sufficient to heat the coolant so that the applicator contact surface is at a desired temperature (about 0°C), and a power supply coupled to the heating element (resistive heating wire), wherein the power supply is controlled with an algorithm, wherein the heating element is positioned to deliver more energy toward the proximal end of the contact surface and further comprising a temperature sensor (9) that monitors the temperature of the contact surface (Figure 1 and col. 1, lines 34-45, col. 2, line 27-col. 3, line 29).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7, 9, 17-20, 22, 26, 27, 30-33 and 35 are rejected under 35 U.S.C.

102(e) as being anticipated by Ingle et al. (6,216,704).

As to claims 1-4, 7 and 9, Ingle et al. disclose a method of controlling the temperature of an applicator with a tissue contact surface placed adjacent to pelvic support tissue, precooling the tissue to about 0°C by circulating a coolant through the applicator, before heating it to a higher temperature by delivering RF energy to at least

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two electrodes (one being considered a “heating element” and the other the claimed “at least one electrode at the contact surface”) while monitoring the temperature of the electrode and adjusting a power level of the energy delivered to the heating element to maintain the contact surface of the applicator at the desired temperature (col. 12, lines 6-47, col. 15, lines 5-40, col. 16, lines 51-61, col. 18, lines 8-68).

As to claims 17-20, 22, 26, 27, 30-33, Ingle et al. disclose an applicator and system where again one electrode is a heating element and another electrode is “at least one electrode” on the contact surface and powered by RF and a cooling assembly that controls the delivery of a coolant at a constant rate and the heating element, a power supply coupled to the heating element and controlled by a temperature control algorithm, wherein the desired temperature can be set as required at about 0°C, and further comprising a temperature sensor for monitoring the temperature of the contact surface.

As to claim 35, Ingle et al. further disclose a processor with a memory programmed to deliver coolant to the applicator, monitoring a temperature of the contact surface, and for controlling delivery of energy to a heating element that controls a temperature of the coolant adjacent the contact surface (col. 15, line 28-col. 16, line 15 and col. 22, lines 45-64).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 28 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ingle et al. in view of Stern (6,413,255). Ingle et al. fail to disclose the coolant comprises R143a refrigerant gas. But, Stern discloses a method an apparatus for treatment of tissue wherein one of many of well known refrigerants is R134a used to cool an electrode (col. 13, lines 9-24). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to look to the device of Stern in the process of selecting a gas suitable for the temperature range required for cooling tissue indirectly by cooling the electrode.

### ***Allowable Subject Matter***

Claims 10-14, 16, 21 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

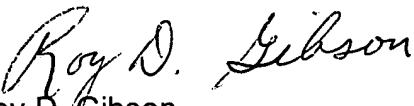
### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Truckai et al. (5,769,880) disclose a an apparatus and method for heating tissue with RF electrodes; and Lee (3,298,371) discloses a freezing probe with an internal heater for the treatment of tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Roy D. Gibson  
Primary Examiner  
Art Unit 3739

June 29, 2005